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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/591,447	04/18/1996	MARIE-JOSE B.J. QUENTIN-MILLET	XI/P02956US0	9198

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EXAMINER
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PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

08/591,447

**Applicant(s)**

QUENTIN-MILLET ET AL.

**Examiner**

Michael Pak

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 79-133 is/are pending in the application.
- 4a) Of the above claim(s) 79-82 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 107, 114, 115 and 125 is/are allowed.
- 6) ☒ Claim(s) 83-106, 108-113, 116-124, 126-133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Response to Amendment***

2. The amendment filed 3 April 2001 has been entered. Claims 83-133 are examined below. Claims 79-82 are withdrawn. Claims 1-78 have been cancelled.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicant's arguments filed 3 April 2001, have been fully considered but they are not found persuasive.

### ***Claim Rejections - 35 USC § 112***

5. Claims 83-106, 108-113, 116-124, and 126-133 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a Tbp2 receptor consisting of SEQ ID NO:2 and 4 or fragments thereof, does not reasonably provide the full scope of enablement for derivatives of Tbp2 receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these

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claims.

Claims 83-106, 108-113, 116-124, and 126-133 encompass Tbp2 derivatives and variants because of the polypeptides are alignment protein with deletion in corresponding region which are clearly delineated. However, the specification fails to teach how to use the derivatives of Tbp2. One skilled in the art cannot predict whether such polypeptides would have any relationship to the TBP2 polypeptide. The state of the art is such that one skilled in the art cannot predict the tertiary structure of protein based on the primary amino acid sequence (Bowie et al.(S)). Thus, it would require undue experimentation to make and use variants with amino acid substitutions in the Tbp2 receptor because one skilled in the art could not predict the effect of the changes due to substitutions on the tertiary structure of the Tbp2 receptor which is necessary to determine if the protein is functional. Furthermore, changes tertiary structure will affect any antibody based on the original epitope of the natural Tbp2 protein found in the bacteria and if the antibody does not recognize the natural Tbp2 protein in the bacteria it cannot be used in diagnostic assay or for vaccination. It would require empirical determination to determine the all variant combinations which are functional because one skilled in the art cannot predict the which combination of variants of Tbp2 receptor would result in a functional polypeptide. Guidance and working examples directed to the Tbp2 receptor in the specification are not predictive of using *any* variants or derivatives of Tbp2 receptor because the changes in tertiary structure affects the protein function in an unpredictable manner. Therefore, in view of the large extent and unpredictable nature of the experimentation which would be involved, one skilled in the

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art could not make and use the full scope of the invention as claimed without undue experimentation.

6. Claims 107, 114-115, and 125 are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
13 September 2005